REMARKS

Reconsideration of this application as amended, is respectfully requested. By this Amendment, independent claims 1, 6 and 14 have been amended to more particularly point out and distinctly claim the subject invention. The addition of "new matter" has been scrupulously avoided. Claims 1-4 and 6-17 remain in this application. Claim 13 was previously withdrawn based upon an initial restriction requirement.

Independent claims 1, 6 and 14 are being amended to further specify that the claimed individualized or agglomerated particles are being kept in contact with the non-adhesive surface of the support as a result of electrostatic forces of attraction between said particles and the support. The specification provides explicit support for these amendments at page 9, line 29 - page 10, line 8.

In the last Office Action, the disclosure was objected to on the grounds that it allegedly lacks a brief description of the drawing figures.

In response, Applicant notes that a brief description of the drawing figures is present in the original specification at page 15, lines 24-27. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this objection.

Claims 1-4, 6-12 and 14-17 stand rejected under 35 USC § 103(a) as allegedly obvious over Fischer (U.S. Patent No. 4,836,217), Counter (U.S. Patent No. 3,837,340), Quisno (U.S. Patent No. 4,788,971) and Carvalho et al. (U.S. published patent application no. 2003/0064088 A1) in view of Schoendorfer (U.S. Patent No. 5,438,984), Axen et al. (U.S. Patent No. 3,645,852) and Polypropylene (on-line article).

This rejection is respectfully but most strenuously traversed for the following reasons.

As a preliminary remark, Applicant notes that seven references have been relied upon by the Examiner which, in Applicant's view, is an indication in itself that the claimed subject matter is indeed unobvious.

Each of the references will now be discussed below.

US 4,836,217 (Fischer)

Fischer describes an occlusive patch to carry out epicutaneous tests, for instance, by using allergen as active substance. In Fischer, however, the active substance is mixed with a polymer having film-forming properties, allowing the homogeneous distribution of the substance on the patch.

Consequently, this document describes a patch comprising a film formed by a polymer in which the active substance is distributed. In other words, the interaction of the substance with the patch requires the presence of a particular film-forming polymer as disclosed in column 3, line 63, "*The vehicle will be selected from among substances having film-forming properties. Usually it is a polymer*", column 4, lines 58-60, "*it has been found essential to choose a film-forming polymer capable of...*", column 4, lines 67-68, "*the vehicle may consist of a mixture of the above-mentioned polymer*" column 5 lines 58-60, "*the test substance is added to a film forming polymer*" and claim 1 "*said film containing as the film-forming substance a film-forming polymer*".

Moreover, as specified in column 5, lines 33-35 of Fischer, "*the choice of film carrier is not in any way critical*" and nothing in this document is disclosed about electrostatic properties of the carrier material.

In contrast, in the present invention, the carrier material is essential since the patch is designed so that electrostatic charges of the carrier interact directly with particles of the active substance to maintain them on this carrier. As recited in claim 1, the support is "*directly covered*

with at least one biologically active substance in the form of individualized or agglomerated particles, said particles being kept in contact with the non-adhesive surface of the support as a result of electrostatic forces of attraction between said particles and the support".

The invention thus allows to use the active substance in a dry form and as individualized or agglomerated particles without any preliminary mix with an excipient to form a film, thereby preventing any alteration of the active substance induced by this excipient.

In summary, Fischer fails to teach how to obtain a patch with an active substance in a dry and native form and as individualized or agglomerated particles without use of any film-forming excipient.

US 5,438,984 (Schoendorfer)

Schoendorfer describes a patch for collecting analytes contained in perspiration of a patient. This patch allows to control the ionization state of collected analytes by using buffer or delivering electricity. It is important to notice that, in this document, the collected substance is in a liquid form, dissolved in perspiration.

Accordingly, Schoendorfer fails to teach how to obtain a patch with a support being directly covered by an active substance in the form of individualized or agglomerated particles.

Furthermore, the skilled artisan would not have combined Fischer and Schoendorfer, considering that the aim of Schoendorfer is completely different. Indeed, the aim of this document is to collect a substance contained in perspiration which is very remote from Fischer, which aims to bring a substance into contact with the skin of a subject.

Accordingly, Schoendorfer fails to suggest the present invention and cannot remedy the deficiencies of Fischer because there is absolutely no disclosure of a solid substance, no suggestion of electrostatic forces, and a different purpose.

US 3,837,340 (Counter)

Counter relates to a patch for immunizing an animal containing a deposit of several dry avirulent viruses.

In this document, it is specified that if the virus is in a powder form, "*this powder is applied to an adhesive spot on the supporting article*" (column 4 lines 19-20). Moreover, all examples illustrate immunizing devices obtained by using virus suspensions applied on a gauze pad or an adhesive bandage and, nothing is disclosed in this document about electrostatic properties of the support.

Furthermore, column 5 lines 15-20 discloses that "*the spread of reinfective exsudate from a resulting pustule should also preferably be minimized*" by "*providing an air space or absorbent material*" in the patch rather than a continuous non-absorbent surface. This means that, in contrast to the present invention, the patch does not form a hermetically closed space between the support and the skin.

US 4,788,971 (Quisno)

This document relates to a patch comprising a sample-retaining housing of inert material. Preferably, this housing contains an absorbent pad to receive the liquid substance of interest, as disclosed, for example, column 3 lines 66-67, "*the patch system comprises a sample-retaining housing and an absorbent pad*".

Therefore, this document describes means to retain liquid substance on the support of the patch but, nothing is disclosed about means to keep substances in the form of individualized or agglomerated particles in contact with a non adhesive surface of the support. In particular, there is no disclosure about electrostatic properties of the support and, on the contrary, in this

document, the support has to be inert, that is to say without any ability to interact with the substance, and thus, without electrostatic properties.

US 2003/0064088 (Carvalho)

Carvalho relates to an implantable drug delivery system hermetically sealed on an organ. This device comprises an isolated drug reservoir presented for example in paragraph [0067] "*a preferred embodiment comprises an isolated drug reservoir*", paragraph [0069] "*the drug reservoir is isolated from adjacent structures and fluids*" and paragraph [0125] "*drug within the reservoir can be associated or mixed with another agent*". This drug reservoir allows fluid transport across the targeted organ surface.

Thus, Carvalho discloses a targeted implantable delivery system for therapeutic agents in a liquid form. This is very different, and very remote from a dermal patch.

Axen (US 3,645,852)

This document relates to a method of binding water-soluble proteins by covalent bonds on a water-insoluble polymer containing one or more groups of the formula –XH which react with a cyanogen halide and the water-soluble protein. This document does not suggest any application of these polymers in the manufacture of a dermal patch. Moreover, in the present invention, the particles of the biologically active substance are maintained on the support by electrostatic forces and not by covalent bonds. Consequently, this document is irrelevant either alone or in combination.

Polypropelene article

This document discloses some physical characteristics of polypropelene and some applications which are very remote from dermal patches. Nothing in this article overcomes the above-noted deficiencies of the other references.

In conclusion, the above-cited documents, either alone or in any combinations, fail to teach a patch as presently claimed, comprising an electrostatic support covered with an active substance in the form of individualized or agglomerated particles kept in contact with the support by electrostatic forces of attraction between these particles and the support.

Indeed, none of these documents teaches the use of electrostatic properties of the carrier in order to obtain a patch with a carrier directly covered with an active substance in the form of individualized or agglomerated particles.

For all of the above reasons, independent claims 1, 6 and 14 are believed to be allowable over the applied prior art. The dependent claims, which all ultimately depend from one of these independent claims, are allowable for the same reasons, as well as for their additional limitations.

Applicant hereby requests that withdrawn claim 13 which is dependent upon independent claim 6 and therefore inherently allowable with claim 6, be reinstated and likewise allowed.

Applicant has recently submitted a supplemental Information Disclosure Statement in order to timely bring to the Examiner's attention the following documents cited in a corresponding Japanese application:

Japanese Unexamined Patent Application No. H06-238008 and,
WO 98/25521.

A copy of the abstract in English of the Japanese application H06-238008 was enclosed with the supplemental IDS.

WO 98/25521 is written in German language but the corresponding US patent is No. 6,142,954.

H06-238008 relates to a patch comprising ethylene fluoride disc-like chambers for supporting an allergen in a liquid form.

WO 98/25521 relates to a patch test plaster for epicutaneous tests comprising a releasable disc-like chamber disposed on an elastic carrier. This chamber contains an absorbent material to receive the active substance in a liquid form.

Thus, these two documents relate to patches comprising chambers to receive the active substance in a liquid form.

Since all outstanding objections and rejections have been fully addressed herein, this application is believed to be in condition for allowance and such action is respectfully requested.

If, after consideration of this response, the Examiner has any remaining reservations about the allowability of this application, he is requested to call Applicant's representative at the below indicated telephone number to schedule an interview.

Respectfully submitted,

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